

REMARKS

Claims 1-16, 18, 21-37 and 39-70 remain pending in the application and were examined in the most recent action. Claims 80-84 are newly added to the application. Claims 19-20, 56, 64-65 and 71-79 are canceled.

The action indicates that claims 1-15, 29, 30 and 32 are allowed. The applicants thank the examiner for this action. The remaining pending claims stand rejected either as being anticipated by or obvious over US 5826174 ('174), US 5023783 ('783), US 6,503,207 ('207), 5,546,956 ('956) and/or 4,62,440 ('440) as set forth in the action.

The applicants do not believe that the cited references make out a prima facie case of anticipation or obvious, as the references, taken either alone or in combination do not teach or suggest each and every limitation of the claims, as they now stand in the application. Reconsideration and allowance is therefore respectfully requested.

Claims 16, 18, 22-24 and 27-28

Claim 16 is rejected in the action as being anticipated by the '174 or '783 patent. As amended, the method recited by claim 16 to objectively test the hearing of a subject using a steady state evoked potential (SSAEP) stimulus includes, among other things, presentation of the stimulus to the subject occurs during a plurality of "stimulus on" intervals during which stimulus waveforms are presented and does not occur during at least one "stimulation off" interval, with the at least one stimulus off interval being between at least two stimulus on intervals.

Neither the '174 nor '783 references anticipate this claim. In each of these references the "on" and "off" duration refers to the stimulus and inter-stimulus segments of the stimulation signal, respectively. This is not what claim 16 recites or requires. As amended, claim 16 defines a "duration during which stimulus waveforms are presented." This aspect of the invention is not shown or suggested in the references and therefore is inventive and novel. Practice of the method or implementation of an apparatus incorporating the method overcomes the issue of harming subjects when presenting ASSR stimuli. Unlike other types of test stimuli (e.g. clicks), the ASSR stimuli are continuously presented and when several tones are presented simultaneously (as may occur in an apparatus or method in accordance with the current invention) this results in even higher RMS energy. Therefore the danger of "blasting" a subject's auditory system becomes an issue. With transient "click" stimuli of

conventional tests, such as described in the '174 and '783 patents, the loudness is not an issue. Therefore, an SSAEP auditory test including at least one SSAEP stimulus and a plurality of stimulus on intervals and at least one stimulus off intervals is not taught or suggested by these references. This type of "time out" does not occur in other tests, and certainly would not occur or be required in traditional auditory tests because non-steady state stimuli do not contain enough energy to make this issue pertinent to the testing. . This issue was not evident to the inventors prior to observing the potential of a patient experiencing tinnitus after a testing period, which prompted this solution. Although commercial ASSR testing systems have existed since 1990, none of the five commercially available ASSR instruments, except that associated with the inventor, have provided the user with the ability to insert these type of automatically invoked "stimulus off" periods into the testing protocol for higher intensity stimuli.

For at least these reasons, the applicants submit claim 16, as amended, is allowable and requests such action. Furthermore, as claim 16 is allowable, claims 18 and 21-24 and 27-28 depending from claim 16 are also allowable. The applicants note that claims 18 and 21-24 are amended to correspond to claim 16, as amended.

Claim 25-26 and 80-84

Claim 25 is amended to place it in independent form. Claims 80-84 are newly added and are dependent from claim 25. Consideration and allowance of claim 25 and its dependent claims is requested.

In accordance with the methods and apparatus embodying such methods encompassed by claim 25, multiple stimuli are tested simultaneously. Claim 25 requires, among other things, individually changing selected components of the signal depending upon test results. For example, if a first test included a stimulus having components of 500, 1000, 2000 and 4000 Hz which were all modulated independently and presented at 60 dB, then the test results might indicate that 500, 1000, and 2000, were significant, while 4000 was not. The next test would present 500, 1000, and 2000 at 60 dB while the gain of the hearing aid for 4000 Hz band is increased so that this component of the stimulus is differentially presented at 70 dB. Alternatively, in the stimulus itself, the 4000 Hz component can be uniquely adjusted so that it is 10 dB louder than the other components. Further, if the steady-state response to the 2000 Hz component is relatively large, then this component can be decreased. This may cause the

ASSR to the 4000 Hz to reach significance (since there is less masking from the 2000 Hz region) and also still enable the 2000 Hz response to remain significant since it was large.

Accordingly, in multiple stimulus testing situations, the characteristics of the hearing aid related to a particular component of the stimulus can be adjusted based upon the test results for the multiple steady-state responses. The idea of differentially and uniquely adjusting characteristics of a hearing aid in relation to the electrophysiological responses related to independent components of a test signal is not anticipated by the cited references, or any references of which the applicant is aware. References describing behavioral testing are inapplicable since the patient can not accurately describe which components of the test stimulus they could hear, and moreover, how well (in any type of quantifiable manner) they could hear each of these components.

Furthermore, none of the references teach or suggest that the characteristics of a hearing aid related to only one component of the test signal are being individually and uniquely adjusted, while the processing of other components of the test signal remain the same or are differentially adjusted. This can only occur when using a test signal with more than one test component. This differential adjustment of the claimed invention is not necessary, and is not taught or suggested by the references, since the characteristic of the test signal, such as volume, could be increased for all components of the test signal (either directly for the stimulus, or in the functional gain setting of the hearing aid).

The applicants submit claim 2The applicants submit claim 25 is allowable and such action is requested. Claim 26 and 80-84 dependent from claim 25 are therefore also allowable, and such action is also requested.

Claims 31 and 35 are similarly amended to amplify and clarify the test signal as having multiple test signal components and the individual adjustment of these components in order to enhance the likelihood of obtaining a response for each test component.

As amended, these claims require, among other things, that the test signal comprise more than one test signal component. The test is conducted with individual adjustment of each test signal component in order to enhance the likelihood of obtaining a response corresponding to that test component. Individual test signal component adjustment and iterative testing, as now clearly set forth in these claims, is not taught or suggested by any of the cited references.

Thus, the applicants submit claims 31 and 35, as amended, are allowable. Claims 31 and 35 are also allowable for the similar reasons claim 25 is allowable as discussed above.

Such action is requested. Allowance is also requested for claims 36-41 that depend from claim 35. The applicants note that claims 36-40 are amended to clarify the manner in which the data is recorded and analyzed.

Claim 42:

The action cites the '174 and '783 patents as rendering claim 42 unpatentable, i.e., obvious. The action describes vision testing methods as being similar to the claimed subject matter. Applicant is not familiar with the vision testing methods raised in the action and respectfully requests clarification of the nature of such methodologies and the correspondence to the claimed methodology, should the rejection be maintained. The action discusses "normalizing" response amplitudes to compensate for processing deficiencies. However, the as claimed adjustment of stimulus amplitude would be done for either normal or abnormal hearing and does not relate to compensation for deficiencies, as suggested by the examiner, but rather to pertains improving the efficiency of the testing paradigm by independently adjusting the intensities of the stimulus components. All stimuli which are simultaneously presented (e.g. 500, 1000, 2000, and 4000) are normally tested at a specific intensity e.g. 60 dB SPL, and then 50 dB SPL. This does not occur according to the invention of the pending claims. For example, an embodiment of a method in accordance with the claims provides for test stimuli which leads to smaller responses (e.g. 500 and 4000 Hz) at higher intensities while testing 1000 and 2000 at lower intensities. In the first test, 500 and 4000 Hz may be tested at 70 dB while 1000 and 2000 are tested at 60 dB. In a second test 500 and 4000 are tested at 60 dB while 1000 and 2000 are tested at 50 dB, etc. Such an embodiment is described at paragraph [0253] of the written description. In a visual test this would be equivalent to testing green and yellow thresholds at the same time and strategically presenting green slightly brighter than yellow in order to decrease testing time, since the test normally continues until both the green and yellow response reach significance for a given stimulus intensity, and this is a waste of time with respect to testing the green stimulus since it's response would (hypothetically) become significant sooner. However, none of the references teach or suggest doing this. Therefore, the applicants request reconsideration and allowance of claim 42 in light of these remarks.

Claim 43:

Claim 43 is amended to clarify that the hearing aid is automatically adjusted during the test to cause at least some of the responses to components of the test stimulus to become significant. In the cited references, the hearing aid is programmed based upon the hearing test. However, the hearing aid is not used during the test itself, as it would be with an apparatus according to claim 43, and is not adjusted in relation to individual components of a multi-component stimulus

Therefore, the applicants submit claim 43 is allowable, and such action is requested.

Claims 44-54

Claims 44 and 49 are amended to clarify the handling of the data. As amended, the claims require, among other things, indexing data for multiple stimuli presented simultaneously so that partially overlapping portions of the data can be combined according to stimulus component and intensity.

To be clear, the test results are not in the table, but rather, the indices pointing to which data segments are assessed in the generation of test results are stored in the table. Instead of relying upon a single data set to calculate an average sweep, as is normally done, multiple averaged sweeps are created using different portions of the data that are selected according to intensity and stimulus combinations used during testing. Also, multiple components can be simultaneously tested at different intensities. None of the cited references teach or suggest such simultaneous component testing at multiple intensities and corresponding data collection and indexing to enable individualized adjustment of test signal components.

As such, the applicants submit claims 44-54 are allowable, and such action is requested.

Claims 55 and 57-62:

Claim 55 is amended to incorporate the limitations of claim 56. Claim 56 is correspondingly canceled.

As amended, claim 55 now requires, among other things, that the modulated signal be steeper than sine modulated signals. That is, the modulated signal will have slopes steeper than sine wave modulated signal slopes and regions between maxima having less energy than corresponding regions of a sine wave modulated signal.

None of the cited references teach or suggest such a modulated test signal. Therefore, the applicants submit claim 55 is allowable. Claims 57-62, dependent from claim 55 are also allowable. Such action is requested.

Claims 63-68:

Claim 63 is amended to incorporate the limitations of claims 64 and 65. Claims 64 and 65 are accordingly canceled.

As amended, claim 63 now requires, among other things, that the testing procedure comprises automatically pausing for a specified time period and presenting an alternate acoustic stimulus to the subject during the time period.

None of the cited references teach or suggest such periodic substitution of the test signal, in order to test certain regions of the auditory system while letting other regions rest. This strategy is more efficient than periodically halting all auditory testing and is only possible because different frequencies are processed by different parts of the auditory system. This realization has not been used before in a manner which capitalizes upon this feature in order to provide rest periods to one part of the auditory system while testing another part of the system. Therefore, the applicants submit claim 55 is allowable. Claims 57-62, dependent from claim 55 are also allowable. Such action is requested.

Claims 69-70:

Claim 69 is amended to clarify the structure of the test signal to include transient components as well as the manner in which the stimulus is presented to the subject and data is gathered. In particular, claims 69 requires, among other things, that response potentials of the subject are stored in data epochs and the transient components occur with a repetition rate that is an integer sub-multiple of the data epochs.

The action cites the '174 and '783 patents as anticipating original claim 69. Neither of these references teach or suggest an SSAEP stimulus having transient components configured with a repetition rate related to data storage epochs. As described at paragraph [0076] of the written description, the "concatenation procedure does not cause discontinuities in the data because the SSAEP stimulus which evokes the SSAEP response is constructed so that each epoch contains an integer number of periods of the SSAEP response."

None of the cited references teach or suggest such a test signal having transient components with a repetition rate that is related to data storage epochs. Therefore, the

applicants submit claim 69 is allowable. Claim 70, dependent from claim 69, is also allowable. Such action is requested.

Claims 71-79:

Claims 71-79 have been canceled as it is believed the subject matter of these claims is now incorporated in other claims now pending in the action. However, the applicant reserves the right to present claims of the same or similar scope in later applications.

Conclusion

In light of the foregoing, the prompt issuance of a notice of allowance is respectfully solicited. Should the examiner have any questions, the examiner is respectfully invited to telephone the undersigned.

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